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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,045	01/03/2002	Jon Elliot Adler	54289US	3276

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT PAPER NUMBER

1649

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,045

Applicant(s)

ADLER ET AL.

Examiner

Michael Brannock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 235-267 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 235-253 is/are allowed.
- 6) ☒ Claim(s) 254-267 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 6/12/06, have been entered in full.

Response to Amendment

On page 8 of Applicant's 6/12/2006 reply, Applicant asserts that the status of claims 257-267 was not addressed in the prior office action. This was a clerical error as the claims depend from claim 254 and should have been included in the rejection and objection regarding that claim.

Specification

The amendments filed 4/29/05 and 12/12/05 are objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: claims 254-267 require constructs containing a genus of G-proteins and GPCRs other than T1R2, yet the specification does not teach such constructs. Further, the specification simply teaches the use of the promiscuous G-protein Gα15 and the GPCR T1R3.

Applicant argues that Gα16 is taught in the specification as being similar Gα15. This argument has been fully considered and considered persuasive in part, i.e. the specification does point to Gα16 as being similar to Gα15. However, regarding the new matter objection, the issue

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is that the claim (e.g. 254) requires that the nucleic acid molecule encoding the GPCR also contains nucleic acid encoding the G-protein. There is no teaching of this either in the specification at [40] or in the prior application U.S. Ser. No. 09/984,292, referred to in paragraph 40. The same situation is true of the additional GPCR, other than T1R2, required in claim 256. Applicant points to Examples 8-11 for implicit support of such constructs. This argument has been fully considered but not deemed persuasive. The examples are ambiguous regarding the nature of the constructs used and do not attempt to explain them. Rather, in Example 12 cells expressing the T1R2/T1R3 receptors were clearly transfected with separate vectors, each encoding T1R2 or T1R3, but not both. Applicant is required to cancel the new matter in the reply to this Office Action.

Rejections:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 254-267 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims require constructs containing a genus of G-proteins and GPCRs other than T1R2, yet such constructs are not taught in the specification e.g. the specification simply teaches

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the use of the promiscuous G-protein $G\alpha 15$ and the GPCR T1R3. Thus, the skilled artisan would not recognize that Applicant was in possession of the claimed genus.

Applicant argues that the claim 255 does not include a requirement that the G-protein functionally associate with the GPCR; thus a written description rejection is improper. This argument has been fully considered but not deemed persuasive. There is no teaching in the specification of a nucleic acid encoding both a GPCR and a G-protein, thus the skilled artisan would not recognize that applicant was in possession of such at the time of filing. Applicant argues the specification makes it clear that the T1R may be screened against different G-proteins to ascertain functional effects thereon. This argument has been fully considered but not deemed persuasive. The skilled artisan would view this teaching as simply an invitation to find such functional G-proteins, but that Applicant was not in possession of such at the time of filing. Applicant argues that T1R has been shown to couple with a variety of G-proteins. This argument has been fully considered but not deemed persuasive. Presumably Applicant is referring to Applicant's prior argument that a multitude of G_i -proteins have been found to couple to T1R receptors. This argument has been fully considered but not deemed persuasive. The specification simply lists a multitude of G-proteins "that could potentially be used", however this disclosure does not put one in possession of those that do.

Applicant argues that Examples 8-11 exemplify and describe constructs containing a T1R2 gene and that of another GPCR. This argument has been fully considered but not deemed persuasive. As discussed above, the examples are ambiguous regarding the nature of the constructs used and do not attempt to explain them. Rather, in Example 12 cells expressing the T1R2/T1R3 receptors were clearly transfected with separate vectors, each encoding T1R2 or

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T1R3, but not both. Further, these arguments do not address the lack of support for the genus of GPCRs when only T1R3 has been disclosed as expressed together with T1R2. Applicant argues that the claim language does not require that the “other” GPCR functionally associate with T1R2. This argument has been fully considered but not deemed persuasive. Although the examiner agrees with Applicant’s assertion, the issue is that the genus encompasses the subgenus of GPCRs that *do* functionally associate with T1R2 and the specification does not contemplate any other subgenus, i.e. the specification does not appear to contemplate the genus of polynucleotides expressing a T1R2 and another polynucleotide that encodes a GPCR other than T1R2 and yet does not functionally associate with the T1R2.

Allowable Subject Matter

Claims 235-253 are allowable.

Additional Reference of note:

US Patent Publication US20030040045A1 is considered relevant to the instant application but is not being relied upon as the basis of any rejection in this Office action. It is noted that US20030040045A1 teaches heterologous expression of the combination of T1R2 and T1R3, and these teachings are fully supported by prior application US60/302898, filed 07/03/01.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX months.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB


August 19, 2006


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER